SEP 2 7 2002 K022297

510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92.

Assigned 510(k) number: K022297.

Submitter

Name: CardioComm Solutions Inc.
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Victoria, B.C., Canada
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Contact: Angela Halwas
Date: July 15, 2002

Device

Name: Global ECG Management System (GEMS)
Substantial Equivalence is claimed to: GEMS (K982384 and K020366)

Description

GEMS is a software product designed for Microsoft Windows 98, Windows NT, and Windows 2000 operating systems running on an IBM compatible platform. GEMS is compatible with industry standard client server database management systems and as such will operate standalone or on a local or wide area networks. GEMS consists of a user interface that enables health care professionals to input, store, and output data from a relational database.

The product consists of a set of modules that can be installed as required to customize the application to individual users' needs. Modular design has the benefit of encapsulating changes within the overall application. If a module changes, then in most cases the change will affect only that module and will not affect the rest of the program. This permits more efficient and controlled development and testing, and prevents new and unknown safety issues and anomalies from being introduced. This stability contributes to the safety and reliability of the product.

GEMS is capable of multi-tasking and supports the linking and embedding of related information objects in the ECG. The software stores all aspects of a patient's cardiology record including: arrhythmia diagnosis, pathological

diagnosis, ECGs, ECG information, physician notes, clinical history, pacemaker/ICD data and associated reports.
Data can be entered via keyboard, mouse, bar code reader, serial port, or IrDA port, and stored to and retrieved from any computer media. Information can be displayed on the computer monitor or printed.
GEMS is not a life-supporting or life-sustaining system. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Intended Use

GEMS is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices, including diagnostic 12-lead devices. Users will be able to purchase specific modules for managing other patient cardiac related data such as pacemaker and rehabilitation data that fit their patients' needs. The ECG module may be licensed to other software developers as an ECG viewer for their products. GEMS is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GEMS does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Technological Characteristics

Only one feature in this modified version of GEMS cannot be found in the predicate device (unmodified version of GEMS): the EASI system for deriving an approximation to a 12-Lead ECG from a 3-channel ECG. The EASI feature only supplies an alternative source for 12-Lead ECGs, which are already supported by the approved (unmodified) device. Thus the modification represents a minor change to the functionality of the product and does not change the indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2002

CardioComm Solutions Inc.
c/o Ms. Angela Halwas
Quality System Manager
201-3060 Cedar Hill Road
Victoria, British Columbia
CANADA V8T 3J5

Re: K022297
Trade Name: Global ECG Management System II (GEMS)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: August 27, 2002
Received: August 30, 2002

Dear Ms. Halwas:

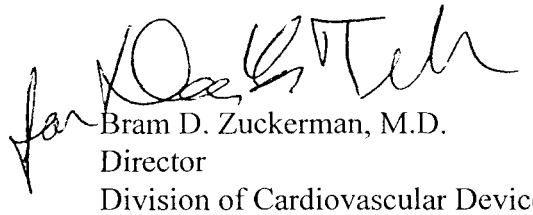
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: K022297

Device Classification Name: Mercator

Device Proprietary Name: GEMS

Indications for use:

GEMS is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices, including diagnostic 12-lead devices. Users will be able to purchase specific modules for managing other patient cardiac related data such as pacemaker and rehabilitation data that fit their patients' needs. The ECG module may be licensed to other software developers as an ECG viewer for their products. GEMS is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GEMS does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

This version of GEMS includes the EASI algorithm for deriving an approximation to a 12-lead ECG from a 3-channel recording (using the lead placement specified in the EASITrak 12 Model 4100 / Zymed Model 4100 / EASI Arrhythmia Event Monitor user manual). If manual ST segment measurements will be made on the approximated 12-lead ECG, the patient population is limited to the following indications:

Ages: 33 to 82 years

Heights: 147 to 185 cm (58 to 73 in)

Weights: 53 to 118 kg (117 to 261 lb)

Height to Weight ratios: 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K022297

Prescription Use ✓